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| 10/781,484 | 02/18/2004 | Rafail Zubok | 532-3X7 | 3112 |

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| EXAMINER |
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WOODALL, NICHOLAS W

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| ART UNIT | PAPER NUMBER |
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3733

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01/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,484

Applicant(s)

ZUBOK ET AL.

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 23-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/25/2007; 10/31/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 09/28/2007.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5 and 27-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/781,504 in view of Gill (U.S. Patent 6,113,637).

Claim 15 of copending application 10/781,504 discloses the invention as claimed except for the first member and the second members having vertebral contact surfaces, fastener holes, and cooperating articulation surfaces. Gill teaches a device comprising a first member and a second member having vertebral contact surfaces, fastener holes,

and cooperating articulation surfaces in order to permit translational and rotational movement between adjacent vertebrae.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner is unable to find any disclosure in the specification or the drawings of the current application showing the first and second fastener holes being threaded.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 26 recites the limitation "at least one of the first and second spaced apart surfaces of the ledge members" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill (U.S. Patent 6,113,637).

Regarding claim 1, Gill discloses a device comprising a first member (22), a first intermediate member (24), and a first insertion plate (76) capable of engaging the first member and the first intermediate member. The first member includes a vertebral contact surface and a first flange (34) that includes a first through hole (right hole 36) capable of receiving a bone screw and a first fastener hole (left hole 36). The first intermediate member includes a vertebral contact surface and a first intermediate flange (58) that includes a second fastener hole (right hole 56) offset from the first fastener hole of the first member with respect to the spinal column, wherein the vertebral contact surface is capable of coupling an endplate of an intermediate vertebral bone adjacent to the first vertebral bone of the spinal column. The first and second fastener holes have a size and a position and are capable of receiving at least one fastener capable of coupling the first insertion plate such that the first member and the first intermediate member are oriented with one another for simultaneous insertion into a first intervertebral disc space defined by the endplates of a first and intermediate vertebral bones. Regarding claim 23, Gill discloses a device wherein each of the first member

and the first intermediate member include articulation surfaces capable of cooperating to facilitate articulation of adjacent vertebral bones while the device is inserted in an intervertebral disc space and wherein the insertion plate is capable to orient the articulation surfaces with one another for simultaneous insertion into the intervertebral disc space.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2-6 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (U.S. Patent 6,113,637).

Regarding claim 5, Gill discloses a device comprising a first insertion plate that includes a base, a first mounting element capable of engaging the first member and a first intermediate mounting element capable of engaging the first intermediate member, wherein the mounting elements are offset with respect to one another relative to a longitudinally directed axis of the bases running substantially parallel to a longitudinal axis of the spine. Regarding claim 25, Gill discloses a device wherein the first insertion plate includes a ledge member (79) extending from a posteriorly directed surface of the base, wherein the ledge has a size and shape capable of extending at least partially between the first member and the first intermediate member such that they may be at least one of into and moved within the intervertebral disc space without substantially

changing their orientation to each other. Regarding claim 26, Gill discloses a device wherein at least one of a first and second spaced apart surfaces of the ledge are contoured and capable of engaging with respective surfaces of the first member and the first intermediate member, wherein at least one of the surfaces of the ledge is curved and at least one surface is flat. Regarding claims 27, 29, and 30, Gill discloses a device further comprising a first insertion member (74) extending away from an anteriorly directed surface of the base of the first insertion plate capable of facilitating movement of members and insertion of the members, wherein the first insertion member is a stem having a size and shape capable of engaging with an insertion handle (72) to further facilitate movement. Regarding claim 2-6 and 25-30, Gill discloses the invention as claimed except for the device further comprising a second member, a second intermediate member, and a second insertion plate (claim 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Gill further comprising a second member, a second intermediate member, and a second insertion plate, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 3, Gill discloses a device wherein the first and second insertion plates are capable of orienting the through holes of the first and second flanges of the device to have a configuration substantially similar to a spinal fusion plate when viewed from at least an anterior vantage point. Regarding claim 4, Gill discloses a device wherein at least one of the first insertion plate is capable of engaging and orienting the

first member and the first intermediate member for simultaneous insertion or the second insertion plate is capable of engaging and orienting the second member and the second intermediate member for simultaneous insertion. Further regarding claim 5, Gill discloses a device wherein the first and second mounting elements do not interfere with one another when the first and first intermediate members are positioned in a first disc space and the second and the second intermediate members are positioned in a second disc space. Regarding claim 6, Gill discloses a device wherein the first intermediate mounting element and the second intermediate mounting element are offset in opposite direction with respect to the longitudinally directed axis of the bases.

13. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (U.S. Patent 6,113,637) in view of Cise (U.S. Patent 6,632,091).

Regarding claims 31 and 32, Gill discloses the invention as claimed except for the stem and the handle being capable of being detached, wherein the handle includes a tapered shaft and the shaft includes a bore that frictionally engage one another. Cise teaches a device comprising a handle with a tapered shaft and shaft comprising a bore that frictionally engage one another in order to allow the handle to be detached and used with other tools. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Gill wherein the handle includes a tapered shaft and the stem includes a bore in view of Cise in order to allow the handle to be detached and used with other tools.

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (U.S. Patent 6,113,637) in view of Wagner (U.S. Publication 2002/0045901).

Regarding claim 24, Gill discloses a device comprising a screw, a bore capable of receiving the screw, and a screw locking mechanism including a lock screw aperture and a lock screw in order to lock the screw to the device. Wagner teaches a device comprising a screw, a bore capable of receiving the screw, and a screw locking mechanism wherein the screw includes a threaded head and the bore includes internal threads in order to lock the screw to the device. Because both Gill and Wagner teach screw locking mechanisms it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one for the other in order to achieve the predictable result of locking the screw to the device.

Response to Arguments

15. Applicant's arguments with respect to claims 1-6 and 23-32 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

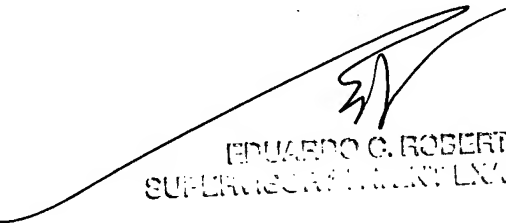
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWWW



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